UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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SERGEANTS BENEVOLENT ASSOCIATION HEALTH AND WEALFARE FUND, NEW ENGLAND CARPENTERS HEALTH BENEFITS FUND, and ALLIED SERVICES DIVISION WELFARE FUND on behalf of themselves and all others similarly situated,

Plaintiffs,

-against-

SANOFI-AVENTIS U.S. LLP, and SANOFI-AVENTIS U.S., INC.

Defendants.

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MEMORANDUM & ORDER

08-CV-0179 (SLT) (RER)

TOWNES, United States District Judge:

On January 18, 2008, Plaintiffs Sergeants Benevolent Association Health and Welfare Fund, New England Carpenters Health Benefits Fund, and Allied Services Division Welfare Fund (collectively "Plaintiffs"), as employee welfare benefit plans, commenced this action under the Racketeer Influenced and Corrupt Organizations Act "(RICO"), 18 U.S.C. § 1962(c) and (d), as well as state law consumer protection statutes and unjust enrichment. Plaintiffs allege that Defendants Sanofi-Aventis U.S. LLP and Sanofi-Aventis U.S., Inc. (collectively "Aventis") fraudulently misrepresented the safety and efficacy of Ketek, a prescription antibiotic. Before the Court is Plaintiffs' motion to certify a class of all third-party payors ("TPPs") who paid or incurred costs for Ketek prescriptions between April 1, 2004 and February 12, 2007.

This Court referred the motion to Magistrate Judge Raymon E. Reyes, Jr. for a report and recommendation ("R&R"). On February 16, 2011, Judge Reyes issued his R&R, recommending that class certification be denied, (Docket No. 133), and Plaintiffs now object to portions of the

R&R. (Docket No. 134). For the reasons set forth below, this Court concludes that Plaintiffs' objections are without merit and adopts the R&R in its entirety.

I. BACKGROUND

This case concerns the prescription antibiotic telithromycin, which was designed, formulated, marketed and sold by Aventis under the brand name Ketek. (Second Amended Complaint ¶ 10). On April 1, 2004, Ketek was approved by the United States Food and Drug Administration ("FDA") for three treatment indications: (1) acute bacterial sinusitis; (2) acute bacterial exacerbations of chronic bronchitis; and (3) community-acquired pneumonia. (Proffer of Facts in Supp. of Pls. Mot. at 66). Plaintiffs allege that to obtain such approval, Aventis fraudulently misrepresented Ketek's safety and efficacy by offering data from a large-scale study, Study 3014, that was plagued with "irregularities," "quality problems," and "protocol violations," (id. at 31, 37), and that Aventis took steps to downplay the defects to the FDA. (Id. at 40, 50, 62).

Plaintiffs also allege that Aventis's marketing campaign broadened Ketek's indications beyond the three for which it had been approved and fraudulently promoted Ketek as being safer and more effective than other antibiotics. (Id. at 77-79). As a result, Plaintiffs claim that they paid for millions of unnecessary Ketek prescriptions and have moved to certify a nationwide class of all TPPs that paid for Ketek between April 1, 2004 and February 12, 2007.[1]

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[1] The proposed class would include:

> All private, non-governmental entities in the United States and its territories that are at risk, pursuant to a contract, policy, or plan, to pay or reimburse, and did pay or reimburse (for purposes other than resale), all or part of the cost of Ketek prescribed, provided, or administered to natural persons covered by such contract, policy, or plan during the period

In the R&R recommending that the motion be denied, Judge Reyes focused his analysis on the RICO claims, noting that their certification would determine jurisdiction over the state law claims. (R&R at 8). Judge Reyes found that the proposed class satisfied the requirements of Rule 23(a),[2] a finding neither party disputes. (Id. at 12-16). Nevertheless, Judge Reyes concluded that causation between the alleged RICO violation and injury, an essential element under RICO, was not common to the proposed class, as required under Rule 23(b)(3). (Id. at 27-32). Relying upon UFCW Local 1776 v. Eli Lilly and Co. ("Zyprexa"), 620 F.3d 121 (2d Cir. 2010), Judge Reyes found that a proposed class must prove its theory of injury through generalized proof, and that the individualized actions of prescribing physicians "had a prohibitive effect" on establishing but-for causation with such proof. (R&R at 30). Additionally, Judge Reyes determined that Zyprexa's discussion of the quantity effect theory, the

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> between April 1, 2004 and February 12, 2007 for uses other than community acquired pneumonia. Such entities include, but are not limited to, insurance companies, union health and welfare benefit plans, entities with self-funded plans that contract with a health insurance company or other entity to serve as a third-party claims administrator to administer their prescription drug benefits, private entities paid by any governmental entity (including a state Medicaid program), and other organizations that paid for all or part of a Ketek prescription for uses other than community acquired pneumonia between April 1, 2004 and February 12, 2007.

(Docket No. 126 Ex. B ¶ 2).

[2] Rule 23(a) provides that:

> One or more members of a class may sue or be sued as representative parties on behalf of all members only if:
> (1) the class is so numerous that joinder of all members is impracticable;
> (2) there are questions of law or fact common to the class;
> (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and
> (4) the representative parties will fairly and adequately protect the interests of the class.

same theory offered by Plaintiffs in this case, was not dictum, and even if it was, the soundness of the Second Circuit's opinion and absence of contrary precedent suggested no reason to decide the matter differently. (Id. at 31-32).

Plaintiffs have timely objected on five grounds, primarily disputing Judge Reyes's reliance upon Zyprexa: (1) that the facts of this case differ substantially from those in Zyprexa; (2) that Zyprexa is contrary to Supreme Court precedent; (3) that Zyprexa is contrary to Second Circuit precedent; (4) that the section of Zyprexa relied upon by Judge Reyes is dictum; and (5) that In re Neurontin Mktg. & Sales Practices Litig., 677 F. Supp. 2d 479, 494 (D. Mass. 2010), is not pertinent to this case. (Pls. Objections at 4-17).

II. DISCUSSION

A. Standard of Review

In reviewing Plaintiffs' objections, this Court applies the standard of review set forth in 28 U.S.C. § 636(b)(1)(C) and Federal Rule of Civil Procedure 72(b)(3). Under both of these provisions, a district court must "make a de novo determination of those portions of the report or . . . recommendations to which objection is made." 28 U.S.C. § 636(b)(1)(C); see Fed. R. Civ. P. 72(b)(3). Upon de novo review, the district court "may accept, reject, or modify, in whole or in part, the findings or recommendations made by the magistrate judge." Id. "The Judge may also receive further evidence or recommit the matter to the magistrate judge with instructions." Id.

B. Rule 23(b) and RICO

Rule 23(b)(3) requires that "the questions of law or fact common to class members predominate over any questions affecting only individual members." In this context, "[c]lass-wide issues predominate if resolution of some of the legal or factual questions that qualify each class member's case as a genuine controversy can be achieved through generalized proof, and if

these particular issues are more substantial than the issues subject only to individualized proof." Zyprexa, 620 F.3d at 131 (quoting Moore v. PaineWebber, Inc., 306 F.3d 1247, 1252 (2d Cir. 2002)).

As the Second Circuit has made clear, "[t]o show injury by reason of a RICO violation, a plaintiff must demonstrate that the violation caused his injury in two senses," namely that it was both the proximate and but-for cause of the injury. Zyprexa, 620 F.3d at 132 (citing First Nationwide Bank v. Gelt Funding Corp., 27 F.3d 763, 769 (2d Cir. 1994); Holmes v. Sec. Investor Prot. Corp., 503 U.S. 258, 268 (1992)). Such causation is often discussed in terms of "reliance" upon misrepresentations. See e.g., Falise v. American Tobacco Co., 94 F. Supp. 2d 316, 335 (E.D.N.Y. 2000) ("[J]ustified reliance on the fraud is necessary to establish causation in fact."). Additionally, the Supreme Court has held that while a plaintiff alleging a RICO violation need not show first-person reliance, he must establish at least third-person reliance in most cases. Bridge v. Phoenix Bond & Indem. Co., 553 U.S. 639, 658 (2008) ("Of course, none of this is to say that a RICO plaintiff . . . can prevail without showing that someone relied on the defendant's misrepresentations.").

In Zyprexa, TPPs ("TPP-plaintiffs") brought a lawsuit against Eli Lilly and Company ("Lilly"), the manufacturer of Zyprexa, alleging that Lilly deliberately misrepresented the drug's efficacy, safety and utility and offered two theories of injury. First, under the "quantity effect theory," TPP-plaintiffs claimed they were injured because they paid for prescriptions that would not have been written absent the fraud; second, under the "excess price theory," TPP-plaintiffs claimed they were injured by the price difference between the fraudulent and actual value of the drug. Zyprexa, 620 F.3d at 129. At a hearing before the district court, TPP-plaintiffs "appear[ed] to have abandoned" the quantity effect theory, see id. at 134-35, and the district court ultimately granted class certification pursuant to Rule 23(b)(3) under the excess price

theory. On appeal, however, TPP-plaintiffs sought to "resurrect" the quantity effect theory, see id. at 134, but the Second Circuit, addressing both theories, reversed certification. With regard to the quantity effect theory – which is at issue here – the Second Circuit found that TPP-plaintiffs could not establish causation through generalized proof because physicians tend to base their prescribing decisions on a plethora of factors, including an "individual patient's diagnosis, past and current medications being taken by the patient, the physician's own experience prescribing Zyprexa, and the physician's knowledge regarding the side effects of Zyprexa." Id. at 135. Additionally, "evidence showed that at least some doctors were not misled by Lilly's alleged misrepresentations" and would not have written excess prescriptions, which "makes general proof of but-for causation impossible." Id. The court also noted that TPP-plaintiffs failed to show that, "had Zyprexa not been prescribed, no medication would have been prescribed," or that an alternative medication "would have been less expensive than Zyprexa." Id. at 135-36 (emphasis in original).

In denying class certification, the Second Circuit ultimately concluded that "the quantity effect theory is no more demonstrable with generalized proof than the excess price theory" because the chain of causation leading from Lilly's alleged misinformation to the eventual prescription sales was interrupted under either scenario. Id. at 136.

C. Plaintiffs' Objections

First, Plaintiffs attempt to differentiate Zyprexa on several factual grounds. They argue that evidence showing Ketek's sales ultimately dropped to virtually zero demonstrates a greater degree of reliance on Aventis's misrepresentations in this case. (Pls. Objection at 5). Plaintiffs further assert that, unlike the TPP-plaintiffs in Zyprexa, as TPPs, they allege direct reliance as TPPs on such misrepresentations. (Id. at 5-6). They also contend that their theory focuses

primarily on the impact of safety information, which physicians always consider for prescriptions, not the issue of overpricing. (Id. at 4).

While there are certain differences between the cases, Plaintiff's examples are of no moment. Although the Second Circuit noted that "prescribing doctors do not generally consider the price of a medication when deciding what to prescribe for an individual patient," Zyprexa, 620 F.3d at 133, that observation does not alter the court's overall finding that the "independent actions of prescribing physicians" disrupt the causal chain under a quantity effect theory and thereby thwart a showing of generalized proof. Id. at 135, 136. Indeed, Plaintiff's expert in this case, Dr. Judith K. Jones, conceded that physicians consider hundreds of individualized, patient-specific factors before deciding which treatment option is best, including, inter alia: sex; age; general allergies; drug allergies; history of present illness; history of past illness; surgical history; reproductive history; family medical conditions; current prescriptions; and smoking history. (Decl. of Dr. Judith K. Jones, dated Mar. 25, 2010, at 7-8). Thus, as in Zyprexa, the proposed class in this case cannot use generalized proof when physicians may have relied upon Aventis's misrepresentations to different degrees, or not at all. Moreover, Plaintiffs assertion that their direct reliance on the alleged misrepresentations distinguishes this case from Zyprexa is unavailing. In either case, after TPPs and pharmacy benefit managers ("PBMs")[3] delineate which drugs will be covered by health care plans, the independent actions of prescribing physicians still break the chain of causation.

Second, Plaintiffs argue that Zyprexa, and by extension Judge Reyes's R&R, disregards Supreme Court precedent by requiring "direct, first-person causation for RICO cases." (Id. at 6-10). As an initial matter, "district courts are bound . . . to follow controlling precedents of the

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[3] The majority of TPPs contract with PBMs to manage the prescription process, including which drugs will be covered by health care plans.

courts of appeals for their circuits." Jackson v. Good Shepherd Servs, 683 F. Supp. 2d 290, 292 (S.D.N.Y. 2009); see also Jenkins v. United States, 386 F.3d 415, 418 (2d Cir. 2004) (noting district courts are bound to apply the law of the relevant circuit court). Moreover, Zyprexa explicitly stated, relying on Supreme Court precedent, that first-party reliance was unnecessary and that third-party reliance would be sufficient to show causation. See Zyprexa, 620 F.3d at 132-33 (citing Bridge, 553 U.S. at 658).

Third, Plaintiffs contend that the Second Circuit overlooked Desiano v. Warner-Lambert Co., an earlier opinion that "recognized the right of [TPPs] to recover from drug companies amounts that were overpaid due to illegal or deceptive marketing practices." 326 F.3d 339, 350 (2d Cir. 2003)). It is Plaintiffs, however, who appear to have overlooked the Desiano court's pivotal statement that "the legal standard of proximate cause that is relevant to the case before us is not the law of RICO; it is, rather, the law of New Jersey." Id. at 348 (emphasis added). Additionally, the statement quoted by Plaintiffs concerned the entirely unrelated question of whether the Desiano plaintiffs should be characterized as direct purchasers or financial intermediaries for purposes of standing. Id. at 350. Desiano is therefore inapposite.

Fourth, Plaintiffs assert that Judge Reyes improperly relied upon dictum in Zyprexa because TPP-plaintiffs had effectively abandoned the quantity effect theory before the district court and it was not properly before the Second Circuit. (Pls. Objections at 10-11). As Judge Reyes noted in his R&R, it is far from clear that "the quantity theory was not before the court in any form" and Plaintiffs argument that "the parties did not brief or argue it" is "patently false." (R&R at 31 (quoting Docket No. 131 at 4 n.1)). Moreover, even if Zyprexa's determination on this issue is dictum, this Court will follow the Second Circuit's persuasive reasoning. See Patsy's Italian Rest., Inc. v. Banas, 508 F. Supp. 2d 194, 209 (E.D.N.Y. 2007) ("[A]s a general principle, a federal district court is required to give great weight to the pronouncements of its

Court of Appeals, even though those pronouncements appear by way of dictum.") (citation omitted); see also United States v. Oshatz, 912 F.2d 534, 540 (2d Cir. 1990) ("[I]n some contexts expressions of views by an appellate court must be regarded as the law of the circuit, even though not an announcement of a holding or even of a necessary step in the reasoning leading to a holding."). In Zyprexa, the Second Circuit devoted comparable attention to the quantity effect theory as it did to the excess price theory, explicitly stating that the former "is no more demonstrable with generalized proof" than the latter. Zyprexa, 620 F.3d 136. This Court finds no compelling justification to disregard that well-reasoned pronouncement.

Fifth, Plaintiffs challenge Judge Reyes's brief citation to In re Neurontin, 677 F. Supp. 2d at 494. The Court need not spend significant ink on this objection as Plaintiffs clearly overemphasize the influence of the case on his R&R.

III. CONCLUSION

For the foregoing reasons, the Court finds Plaintiffs' objections (Docket No. 134) without merit and adopts Judge Reyes's report and recommendation (Docket No. 133) to deny Plantiffs' motion for class certification (Docket No. 111) in its entirety.

SO ORDERED.

S/Sandra L. Townes

SANDRA L. TOWNES
United States District Judge

Dated: March 30, 2011
Brooklyn, New York